

REMARKS

1. Examiner rejected claims 1-18 as being indefinite under 35 USC 112, second paragraph.
2. Applicant has amended the claims to correct all of the deficiencies noted by Examiner. Claims 1-18 are therefore submitted as being patentable under 35 USC 112, second paragraph.
3. Examiner rejected claims 1-7, 9, 11-13, 15 and 18 under 35 USC 103(a) as being unpatentable over Katsumata (US 5,078,149).
4. Claims 1-7, 9, 11-13, 15 and 18 recite an interface device with a distinctly different structure than that disclosed by Katsumata.

Applicant's invention, as recited in claim 1, includes a reservoir with an open proximal end to receive an ultrasound transducer and a distal end closed by a scan window made of a solid, non-flowable hydrogel and *filled with a fluid acoustic coupling medium*.

Katsumata, by contrast, discloses an ultrasound coupler that uses an ultrasonic wave propagating member *made entirely of a solidified polymeric gel*.

This is true of each and every example of the ultrasound coupler disclosed in the Katsumata reference. See FIGS. 1A, 1, B, 2A, 2B, 2C, which depict prior art ultrasound couplers, and FIGS. 5, 7, 8B, 9, 10A, 10B, 11A, 11B, 12A, 12B, which depict various embodiments of the invented ultrasound coupler.

Katsumata also discloses a method of manufacturing the ultrasound coupler, various embodiments of which are depicted in FIGS. 3, 4A, 4B, 6A, 6B, 6C, 8A. The holder 12 is partially filled with an aqueous solution of a water-soluble polymeric compound 14, lower and upper lids 13, 16 are used to contain the solution, and then the solution is

cross-linked to form a solidified elastic ultrasonic wave propagating member 17. The finished ultrasound coupler with the solidified elastic ultrasonic wave propagating member 17 is shown in use in FIG. 5. (See Katsumata, col. 8, lines 47-68 and col. 9, lines 1-14.)

At no point does Katsumata disclose or in any way suggest an ultrasound coupler with a reservoir holding a fluid acoustic coupling medium and a solid, non-flowable scan window.

Katsumata, in fact, teaches away from this claimed configuration, disclosing only examples of ultrasound couplers using elastic ultrasonic wave propagating members made entirely from solid cross-linked polymeric gel.

For these reasons, claim 1, and claims 2-7, 9, 11-13, 15 and 18 which depend from it, are submitted as being patentable over Katsumata under 35 USC 103(a).

5. Regarding Examiner's comments about claim 1 on page 3, lines 18-20, of the Office Action – Contrary to Examiner's assertions, Katsumata does not disclose a fluid tight seal around the transducer. The section cited by Examiner (col. 9, lines 1-10) makes no mention of this feature. Furthermore, since the elastic ultrasonic wave propagating member 17 of Katsumata is made entirely from solid cross-linked polymeric gel, it would not be obvious for any reason to include this feature in the ultrasound coupler of Katsumata. Examiner is respectfully requested to withdraw these grounds of rejection.
6. Regarding Examiner's comments about claim 3 on page 4, lines 1-7, of the Office Action – Examiner should be more cautious of citing to ephemeral and unreviewed sources, such as articles on the Internet. The article could not be found at the url that Examiner cited, but an Internet search found the article at the url:

<http://www.cis.rit.edu/research/ultrasound/ultrasoundintro/ultraintro.html>

With all due respect to the author, Dr. Maria Helguera of the Rochester Institute of Technology, the cited article contains significant technical errors in the section on ultrasound signal attenuation. Furthermore, it appears that Examiner has compounded these errors by copying an incorrect equation incorrectly. This is not a case where two wrongs make a right. In consequence of these errors, Examiner has drawn incorrect conclusions about the Katsumata reference. In light of the obvious technical errors on which they are based, Examiner is respectfully requested to withdraw the grounds of rejection related to claim 3.

7. Regarding Examiner's comments about claim 9 on page 4, lines 17-20, of the Office Action – Contrary to Examiner's assertions, Katsumata does not disclose that the length of the device past the transducer is adjustable to allow adjustment of the position of the transducer focus. The section cited by Examiner (col. 11, lines 52-58) in fact teaches the exact opposite of this. The structure of the ultrasound coupler is configured to *“prevent the otherwise possible deviation in the relative positions of the ultrasonic probe and the ultrasonic coupler.”* Examiner is respectfully requested to withdraw the grounds of rejection related to claim 9.
8. Regarding Examiner's comments about claim 11 on page 5, lines 1-2, of the Office Action, contrary to Examiner's assertions, Katsumata does not disclose a curve on the distal end to approximate the radius of the eye. The section cited by Examiner (col. 4, lines 45-52) actually refers to convex or concave contours on the *lateral surfaces* of the elastic acoustic medium and matching contours on the immobilizing member. Consequently, Examiner is respectfully requested to withdraw the grounds of rejection related to claim 11.
9. Regarding Examiner's comments about claim 13 on page 5, lines 6-7, of the Office Action – Contrary to Examiner's assertions, Katsumata does not disclose a device incorporating delivery of fluid. Element 63 actually occurs twice in FIG. 8B, which was cited by Examiner. In one case, it refers to *“a stopper part 63 is formed in the*

ultrasonic wave propagating member 57 by digging at least one depressed part 62 wholly or partly in circumference in the inner wall of the holder 52.” In the other case, it refers to “*a surface 61 [misabeled 63 in the drawing] of the ultrasonic wave propagating member 57 for contact with a subject 60.*” See Katsumata, col. 9, lines 38-51. In neither case does it refer to a device incorporating delivery of fluid to a distal surface of a scan window. This supposed feature in Katsumata was entirely Examiner’s fabrication based on hindsight from Applicant’s own application. Consequently, Examiner is respectfully requested to withdraw the grounds of rejection related to claim 13.

10. Examiner rejected claim 8 under 35 USC 103(a) as being unpatentable over Katsumata (US 5,078,149) in view of Matthews (US 3,939,123).
11. Applicant submits that additional information regarding material compositions found in Matthews does not add or suggest any of the limitations that are missing from the Katsumata reference as discussed above. Specifically, Matthews does not disclose or in any way suggest an ultrasound coupler with a reservoir holding a fluid acoustic coupling medium and a solid, non-flowable scan window. Therefore, the combination of Katsumata and Matthews does not make obvious Applicant’s claimed invention.

Furthermore, while Matthews describes polyisocyanate terminated polyols to form hydrogels, neither Matthews nor Katsumata teaches whether such copolymers containing alkyleneoxy block segments would have low ultrasound attenuation properties as compared to the water soluble polymers described by Katsumata.

Katsumata teaches only that higher water content results in lower ultrasound attenuation (col. 8, lines 9-14). However, Applicant’s investigations have shown that ultrasound signal attenuation is affected by other factors than just water content. For example, as described in Applicant’s specification, polyHEMA, a water soluble acrylic polymer also described by Katsumata, was found to have a signal loss of 10.62 dB/mm at a water

content of 60% at an ultrasound frequency of 62 MHz. However, the polyurethane hydrogel of Applicant's invention, with a lower water content of 50% (expected to be worse for transmission from the teachings of Katsumata), demonstrated a superior 12 times lower signal loss of 0.88 dB/mm. Clearly ultrasound transmission signal loss at high frequencies is not as simple as just water content of the transmission window.

Therefore, Applicant submits that claim 8 is novel and nonobvious over Katsumata, Matthews and any combination thereof. Allowance of claim 8 is respectfully requested.

12. Examiner rejected claims 10 and 14 under 35 USC 103(a) as being unpatentable over Katsumata (US 5,078,149) in view of Puech (US 6,837,855).
13. Applicant submits that any additional information regarding distance of focus range and ultrasound frequency found in Puech does not add or suggest any of the limitations that are missing from the Katsumata reference as discussed above. Specifically, Puech does not disclose or in any way suggest an ultrasound coupler with a reservoir holding a fluid acoustic coupling medium and a solid, non-flowable scan window. Therefore, the combination of Katsumata and Puech does not make obvious Applicant's claimed invention. Applicant submits that claims 10 and 14 are novel and nonobvious over Katsumata, Puech and any combination thereof. Allowance of claims 10 and 14 is respectfully requested.
14. Examiner rejected claim 16 and 17 under 35 USC 103(a) as being unpatentable over Katsumata (US 5,078,149) in view of de Juan et al. (US 2001/0029335).
15. Applicant submits that additional information regarding addition of a surgical instrument found in de Juan does not add or suggest any of the limitations that are missing from the Katsumata reference as discussed above. Specifically, de Juan does not disclose or in any way suggest an ultrasound coupler with a reservoir holding a fluid acoustic coupling medium and a solid, non-flowable scan window. Therefore, the

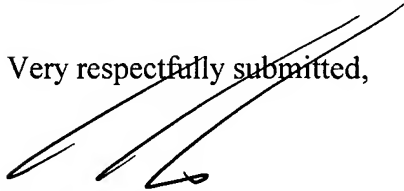
combination of Katsumata and de Juan does not make obvious Applicant's claimed invention. Applicant submits that claims 16 and 17 are novel and nonobvious over Katsumata, de Juan and any combination thereof. Allowance of claims 16 and 17 is respectfully requested.

CONCLUSION

For all the reasons above, Applicant submits that the claims all define novel subject matter that is nonobvious. Therefore, allowance of these claims is submitted to be proper and is respectfully requested.

Applicant invites the Examiner to contact Applicant's representative as listed below for a telephonic interview if so doing would expedite the prosecution of the application.

Very respectfully submitted,

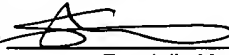


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Date: June 30, 2008